TAB A

PATENT
Attorney Docket No. VACCINE-07083

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	David R. Milich *et al.*		
Serial No.:	10/630,070	Group No.:	1648
Filed:	07/30/2003	Examiner:	Salvoza, M.F.C.
Entitled:	**Rodent Hepatitis B Virus Core Proteins As Vaccine Platforms And Methods Of Use Thereof**		

ORIGINAL

DECLARATION UNDER 37 C.F.R. § 1.132

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTED BY FACSIMILE - CAL 2/20/07

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: 2/20/2007 By: Charlotte A. Eckert

Dear Sir or Madam:

I, DARRELL L. PETERSON, (name) hereby declare and state, under penalty of perjury, that:

1. I am an individual having expertise in producing hepadnavirus core particles as epitope carriers. I am the subject of the attached Curriculum Vitae (Tab 1) and author of the publications shown on the list attached thereto. On the basis of the information and facts contained in these documents, I submit that I am qualified to speak on the level of ordinary skill in the art of the claimed invention.

2. I am familiar with the Office Action dated August 10, 2006 in regard to the above-named patent application and confirm that I have read and understand pending claims.

3. In this Office Action, the Examiner rejected Claims 1-12 and 16-20 as allegedly unpatentable over Pumpens *et al*, *Intervirology*, 38:63-74, 1995 (Pumpens); and rejected Claim

13 as allegedly being unpatentable over Pumpens, in view of Zlotnick *et al., Proc Natl Acad Sci USA.* 94.9556-9561, 1997 (Zlotnick). The Examiner argues that it:

> would be obvious to one or ordinary skill in the art that SEQ ID NO:38, which matched the published sequence for WHV as published by Galibert [*et al., Virology*, 41:51-65, 1982] to use the core molecule as an epitope carrier as described by Pumpens because of the strong similarity of WHC core antigen to the human counterpart.
>
> One of ordinary skill in the art would have expected to achieve a hepatitis B virus core antigen sequence as an epitope carrier based on the WHV sequences because the techniques involved were well developed at the time of applicant's invention (Office Action, page 6).

4. In contrast to the Examiner's conclusion, one of skill in the art at the time the application was filed would not be motivated to substitute woodchuck hepadna virus core antigens (WHcAg) for human hepatitis B virus core antigens (HBcAg) for the purpose of producing an epitope carrier on the basis of the modest structural conservation between these structures as taught by Pumpens. In addition, one of skill in the art would not possess a reasonable expectation of success in achieving an antigenic compositon comprising a WHcAg as an epitope carrier on the basis of a 70% sequence identity between WHcAg and HBcAg. Some reasons that support this contention are discussed below:

Prior to this subject patent application the success rate for insertion of foreign epitopes onto the hepatitis B core (HBcAg) and assembly into hybrid-HBcAg particles was less than 50% as acknowledged by all practitioners of this technology including Birkett, Pumpens ,Zlotnick and myself. The inventors of the technology described in this patent application have increased the success rate to over 90% by using rodent hepadnavirus core proteins including the woodchuck core (WHcAg). Specifically, Birkett lists a large number of epitopes which he failed to insert and which did not allow assembly of hybrid-HBcAg particles using the HBcAg as a platform (Table 7 of US Patent applications 09/931,325 ; 09/930,915 and PCT 01/25625). In contrast, the inventors of the technology described in this application were successful in inserting 3 of 3 exemplary epitopes that were on the list of failures of Birkett using the WHcAg platform (Paragraph [0306] and Table 8).If use of the WHcAg as a vaccine platform was an obvious way of circumventing the severe assembly problems inherent in the use of the HBcAg and of raising the success rate from less than 50% to over 90%. why didn't Birkett, Pumpens, Zlotnick or other practitioners at the time attempt to use the WHcAg during the nearly 20 years of experimentation with the HBcAg ? To my knowledge there was no attempt to insert foreign epitopes into the WHcAg prior to the work described in this patent application.

In my opinion the practitioners of the HBcAg technology did not even try using the WHcAg because the ability of the WHcAg to tolerate insertions of foreign epitopes and the immunologic data regarding the enhanced immunogenicity, non-crossreactivity and general superiority of the

WHcAg were not known at the time. In fact, the only reference by the HBcAg practitioners to the WHcAg in papers and patent applications was a general and mistaken statement regarding the " similarity" of the WHcAg to the HBcAg. This assumption of " similarity " was not based on any experimental evidence. In fact, even the evidence at the time did not suggest "similarity " given the 33% amino acid difference between WHcAg and HBcAg and given the fact that the WHcAg is derived from a non-human pathogen unlike the HBcAg. The inventors of the technology described in this patent application demonstrated for the first time and experimentally that the WHcAg is NOT similar to the HBcAg in terms of its immunologic properties (ie., enhanced immunogenicity, non-crossreactivity to HBcAg at the T cell and B cell levels) and in terms of its superior
function as a vaccine carrier platform (ie., over 90% success rate versus the less than 50% success rate using the HBcAg).

The basic scientific information relevant to the use of the WHcAg as a vaccine platform was unknown prior to this application and similarly the advantages could not have been known, therefore, no expectation of success was present prior to this application and it was therefore not obvious to use the WHcAg as a vaccine platform. The best proof of this principle is the fact that prior to this application no attempt had been made to use the WHcAg or other rodent hepadnavirus core proteins as vaccine platforms.

5. I further declare that all statements made herein are of my own knowledge, are true, and that all statements are made on information and belief that are believed to be true; and further that these statements are made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application of any patent issued thereon.

Dated: 13 Feb 2007 By: Darrell J Peterson

Signature

Darrell J Peterson

Name

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function as a vaccine carrier platform (ie., over 90% success rate versus the less than 50% success rate using the HBcAg).

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5. I further declare that all statements made herein are of my own knowledge, are true, and that all statements are made on information and belief that are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application of any patent issued thereon.

Dated: _____ By: _____
Signature

_____
Name

TAPD

CURRICULUM VITAE

1. **PERSONAL INFORMATION:**

1.1	**NAME:**	Darrell Lynn Peterson
1.2	**DATE AND PLACE OF BIRTH:**	March 2, 1944; Pittsburg, KS
1.3	**CITIZENSHIP:**	United States
1.4	**SOCIAL SECURITY NUMBER:**	
1.5	**MARITAL STATUS/CHILDREN:**	Married/two children
1.6	**HOME ADDRESS/TELEPHONE:**	4345 Roundhill Drive Chesterfield, VA 23832 (804) 276-9354
1.7	**OFFICE ADDRESS/TELEPHONE:**	Department of Biochemistry Room 212 Virginia Biotechnology Center Box 980614 MCV Station Richmond, VA 23298 (804) 828-5614

2. **LICENSURE:** NOT APPLICABLE.

3. **EDUCATION:**

PhD, Biochemistry, University of Notre Dame, 1970
BS, Biology, University of Notre Dame, 1966

4. **MILITARY SERVICE RECORD:**

U.S. Army, September 16, 1970 through March 20, 1972; Honorable Discharge

5. **POSTDOCTORAL TRAINING:**

University of Iowa. Post Doctoral Fellow (NIH), Department of Biochemistry, April 1972 through June 1975 (with Dr. R.L. Blakley).

6. **ACADEMIC APPOINTMENTS:**

University of California, San Francisco. Assistant Research Biochemist, June 1975 through June 1978 (with Dr. G.N. Vyas).

Virginia Commonwealth University. Department of Biochemistry, Assistant Professor, July 1978 through June 1984.

Virginia Commonwealth University. Department of Biochemistry, Associate Professor, July 1984 to 1990.

Virginia Commonwealth University. Department of Biochemistry, Professor, July 1990 to present.

7. **MEMBERSHIP - SCIENTIFIC, HONORARY AND PROFESSIONAL SOCIETIES:**

American Society of Biological Chemists.
American Chemical Society.

8. **MEMBERSHIP IN COMMUNITY ORGANIZATIONS:**

Irrelevant

9. **SPECIAL AWARDS, FELLOWSHIPS AND OTHER HONORS:**

9.1 **Awards:**

9.2 **Fellowships:**

National Science Foundation Predoctoral Fellowship, 1966-1970.
National Institutes of Health Postdoctoral Fellowship, 1972-1975.

9.3 External Grants:

NIH AI15955 Structure of Hepatitis B Proteins.

NIH GM28143 (Jun 1980-Jun 1983) Physical and Structural Studies of Hydroxymethylases. Co-Investigator with Verne Schirch. ($120000)

CIT Grant (Sep 1985-Aug 1986) Molecular Biological Approaches to the Understanding of the Antigenic Structure of Hepatitis B Surface Antigen. ($55000 CIT/$55000 Matching Industrial Support, Abbott Laboratories)

US Spain Cooperative Grant (NSF) CCA 8510-034, 1985-1988, $120000

CIT Grant (Sep 1989-Aug 1991) Development of a Field Assay for Equine Infectious Anemia Virus. ($47000 CIT/$47000 matching industrial support (Centaur Inc.)

NATO Grant (for cooperative project with L. Aggerbeck, Gif sur Yvette, France) 1984-85. $5000, travel only.

Johnson & Johnson Focused Giving Award 1992-1993 ($170,000)

9.4 Invited Seminars:

INVITED PRESENTATIONS AT MEETINGS

1978 International Symposium on Viral Hepatitis (San Francisco)
1984 World Health Organization Meeting on Production of Hepatitis B vaccine in Mammalian Cells (Geneva)
1984 Pan American Biochemistry Congress, Buenos Aires, Argentina
1987 International Symposium on Viral Hepatitis (London)
1989 International Symposium on Viral Hepatitis (Shanghai)
1990 AASLD Single Topic Conference: Immunology and the Liver (Washington, DC)

INVITED SEMINARS AT OTHER INSTITUTIONS

UNIVERSITIES/RESEARCH INSTITUTES

National Institutes of Health, Infectious Diseases 1984

Pasteur Institute, Department of Molecular Virology, Paris, France, 1985

Molecular Genetics Center, National Center of Scientific Research, Gif-sur-Yvette, France, 1985

College of William and Mary, 1986

University of Missouri, Kansas City, MO. 1987

Old Dominion University, 1990

University of Maryland, 1992

INDUSTRIES

Genentech, South San Francisco 1983
Abbott Laboratories, North Chicago, IL 1984, 1986, 1988
AmGen, Thousand Oaks, CA 1987
Biotronics Systems, Inc. Rockville, MD 1988, 1990
Symbiotics Inc., San Diego, CA 1990
Ortho Diagnostics, Inc, Raritan, NJ 1991, 1995
Phytera, Inc. Worcester MA 1995

10. MAJOR COMMITTEES:

10.1 University/Department:

Four Year I&I Curriculum Review Committee
Biochemistry Seminar Series Coordinator 1990-present

10.2 Professional--Panel, Boards, Councils:

National Research Council committee member for the awarding of NSF predoctoral fellowships NIH ad hoc member of various review panels

11. OTHER SIGNIFICANT SCHOLARLY, RESEARCH OR ADMINISTRATIVE EXPERIENCE:

11.1 Graduate Students Trained:

Deborah Paul
Eloisa Guerrero
Pam Hannaman
James Lam
Beth Ann Antoni
Pei-sheng Hu
Jian Zheng
Sue Delos
Ashley Birkitt
Manisha Datta
Kevin Leach

11.2 Postdoctoral Trainees:

Francisco Gavilanes
Maria Teresa Villar-Lecumberi
Julian Gomez

11.3 Major Teaching Assignments:

Graduate Biochemistry (Bic 503-4) 1978-1981, 1995-present.
Undergraduate Biochemistry 1982-1985; 1997-present
Enzymology 1986-present
Bioorganic Chemistry 1987-88
M1 Biochemistry (1996)

12. BIBLIOGRAPHY:

12.1 Papers Published:

1. Martinez-Carrion, M., Tiemeier, D.C. and Peterson, D.L.: The structure and enzyme-coenzyme relationship of supernatant aspartate transaminase after dye sensitized photooxidation. J. Biol. Chem., 245:799-805, 1970.

2. Peterson, D.L. and Martinez-Carrion, M.: The mechanism of transamination: Function of the histidyl residue at the active site of supernatant asparatate transaminase. J. Biol. Chem., 245:806-813, 1970.

3. Martinez-Carrion, M., Tiemeier, D.C. and Peterson, D.L.: Conformational properties of the isoenzymes of aspartate transaminase and the enzyme-substrate complexes. Biochemistry, 9:2574-2582, 1970.

4. Casey, F.B., Eisenberg, J., Peterson, D.L. and Pieper, D.: Altered antigen uptake and distribution due to exposure to extreme environmental temperatures or sleep deprivation. RES, 15:87-95, 1974.

5. Gleisner, J.M., Peterson, D.L. and Blakley, R.L.: The amino acid sequence of dihydrofolate reductase from S. faecium and the position of the reactive methionine residues. Proc. Natl. Acad.Sci. USA, 71:3001-3005, 1974.

6. Gleisner, J.M., Peterson, D.L. and Blakley, R.L.: The structure of dihydrofolate reductase: Partial sequence and the order of the limited tryptic and cyanogen bromide peptides. J. Biol. Chem., 250:4937-4944, 1975.

7. Peterson, D.L., Gleisner, J.M. and Blakley, R.L.: The structure of dihydrofolate reductase from S faecium: The amino acid sequence of peptide CNBr-7 and the complete sequence of the enzyme. J. Biol. Chem., 250: 4945-4954, 1975.

8. Peterson, D.L., Gleisner, J.M. and Blakley, R.L.: Bovine liver dihydrofolate reductase: Purification and properties of the enzyme. Biochemistry, 14:5261-5267, 1975.

9. Vyas, G.N., Roberts, I., Peterson, D.L. and Holland, P.V.: Nonspacific test reactions for antibodies to hepatitis B surface antigen in chronic HBsAg carriers. J. Lab. Clin. Med., 89:428 -432, 1977.

10. Peterson, D.L., Roberts, I.M. and Vyas, G.N.: Partial amino acid sequence of two major component polypeptides of HbsAg. Proc. Natl. Acad. Sci. USA, 74:1530-1534, 1977.

11. Luan Eng Lie-Injo, Ganesan, J., Randhawa, Z.I., Peterson, D.L. and Kane, J.P.: Hb Leiden-B thalassemia in a Chinese with severe hemolytic anemia. Am. J. Hematology, 3:325, 1977.

12. Vyas, G.N., Peterson, D.L., Townsend, R.M., Damle, S.R. and Magnius, L.O.: Hepatitis B 'e' antigen: An apparent association with lactate dehydrogenase isozyme 5. Science, 198:1068 -1070, 1977.

13. Lie-Injo, L., Ganesan, J., Randhawa, Z.I., Kans, J. and Peterson, D.L.: Hemoglobin TAK in a newborn malay. Hemoglobin, 1:747, 1977.

14. Schirch, L. and Peterson, D.: Purification and properties of mitochondrial serine hydroxymethyltransferase. J. Biol. Chem., 255:7801-7806, 1980.

15. Peterson, D.L.: Isolation and characterization of the major protein and glycoprotein of hepatitis B surface antigen. J.Biol. Chem., 256: 69756983, 1981.

16. Peterson, D.L., Nath, N. and Gavilanes, F.: Structure of hepatitis B surface antigen: Correlation of subtype with the amino acid sequence and location of the carbohydrate moiety. J.Biol. Chem., 257:10414-10420, 1982.

17. Gavilanes, F., Gonzalez-Ros, J. Manuel and Peterson, D.L.: Structure of hepatitis B surface antigen: Characterization of the lipid moiety. J. Biol. Chem., 257:7770-7777, 1982.

18. Dreesman, G., Sparrow, J.T. and Peterson, D.L.: Antibody to hepatitis B surface antigen after a single inoculation of uncoupled synthetic HBsAg peptides. Nature, 295:158-160, 1982.

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21. Gavilanes, F., Peterson, D.L., Bullis, B. and Schirch, L.: Structure and Reactivity of cysteine residues in mitochondrial serine hydroxymethyltransferase. J. Biol. Chem., 258:13155-13159, 1983.

22. Barra, O., Martini, F., Angelaccio, S., Bossa, F.,. Gavilanes,F., Peterson,D., Bullis, B. and Schirch, L.: Sequence homology between prokaryotic and eukaryotic forms of serine hydroxymethyltransferase. Biochem. Biophys. Res. Comm., 116:1007-1012, 1983.

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26. Aggerbeck, L.P. and Peterson, D.L.: Electron Microscopic and Solution X-ray Scattering Observations on the Structure of HBeHg. Virology 141: 155-161, 1985.

27. Milich, D.R., Peterson, D.L., Lerner, R.A. and Chisari, F.V.: Genetic Regulation of the Immune Response to HbeAg. J. Immunology 134:396-407, 1985.

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29. Paul, D.A., Purcell, R.H. and Peterson, D.L.: Use of Monoclonal Antibodies to Determine if HBxAg of Mixed Subtype is One Particle or Two. J. Virol. Methods, 13:43-53, 1986.

30. Peterson, D.L.: The structure of hepatitis B surface antigen and its antigenic sites. Bioessays, 6:258-262, 1987.

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34. Hu, Peisheng and Peterson, D.L.: Use of Monoclonal and Antipeptide Antibody to Study the Structure and Arrangement of the Pre-S Proteins of Hepatitis B Surface Antigen. Viral Hepatitis and Liver Disease (A.I. Zuckerman, Ed.) Alan R. Liss, pp. 318-322, 1988.

35. Guererro, E., Gavilanes, F., Peterson, D.L.: Model for the Protein Arrangement in HBsAg Particles Based on Physical and Chemical Studies. Viral Hepatitis and Liver Disease, (A.J. Zuckerman, Ed.) Alan R. Liss, pp. 606-613, 1988.

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PATENTS

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